FactoryTalk PharmaSuite 11.01.00

Quality Document

This document contains information which is confidential and proprietary.

Contents

Introduction

This document summarizes the quality-related planning activities and results for FactoryTalk PharmaSuite 11.01.00 to support further customer-related qualification and validation activities. Other planning activities and results are not covered within this document.

The product development followed

- Good Engineering Practices
- Good Testing Practices
- Good Documentation Practices
- Supplier Good Practices

Regarding quality assurance and verification, the product has been developed following a scalable science-based verification process that is fully compliant with the Quality Risk Management as described in ICH Q9 [1] and the risk-based test approach as described in GAMP® 5 [2].

A 2-step approach was used to analyze the system impact and assess the risk of any system change.

The basic development and verification approach as well as the product life-cycle are mainly defined in two internal documents, the Project Plan [17] and the Testing Guideline [15] (with project-specific aspects described in the Test Plan [18]).

Note: Internal documents are confidential and will only be shown to external parties during an official audit.

The underlying processes are defined in a mature Quality Management System [12].

Note: Specific terms and abbreviations are explained in chapter *Glossary & Abbreviations*.

Life-Cycle Methodology

General Development Model

FactoryTalk PharmaSuite 11.01.00 has been developed using the Agile Product Delivery approach of the SAFe framework provided by Scaled Agile. The ART and Team events create a closed-loop system to keep the train on the tracks, see *Figure 1*. This approach is based on (i) iterations (typically lasting three weeks each), (ii) a prioritized product backlog, and (iii) review, retrospective, and planning meetings per iteration. As a result, each iteration produces a potentially shippable product. The last <no. of> iterations were reserved for final verification and clean-up activities.

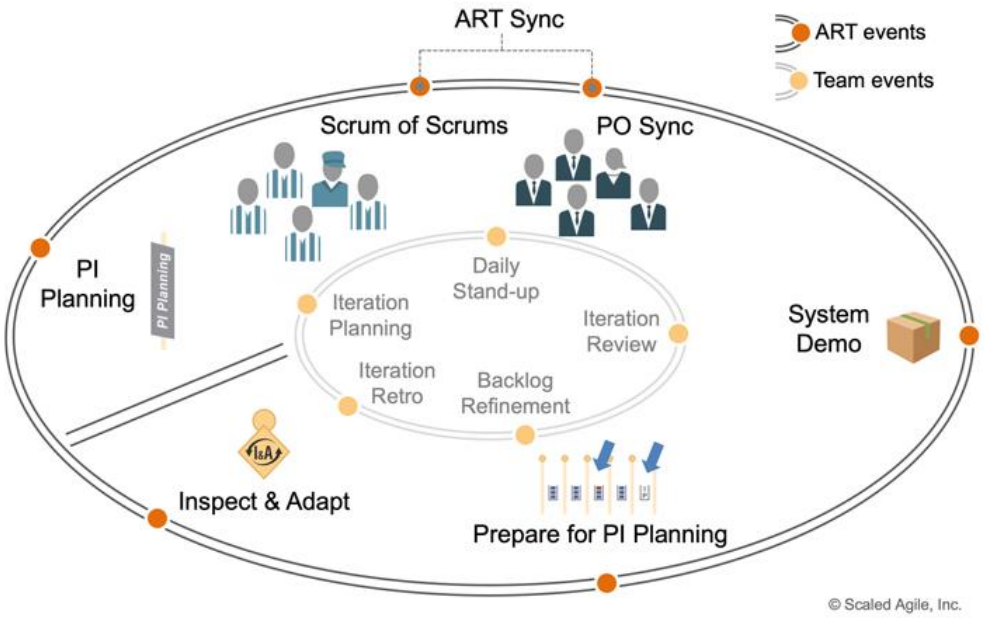

Figure 1: ART events (© Scaled Agile, Inc.)

Requirements Engineering

The specification artifacts are described in detail in a separate chapter *Specification Artifacts* on page 5.

Roles and Responsibilities

A list of stakeholders and all personnel involved in designing, coding, testing, and documenting FactoryTalk PharmaSuite 11.01.00 is provided in section 5.1 of the Project Plan [17].

Development: Design and Coding

Procedural aspects regarding design reviews and code reviews are provided in sections 6.2.4 and 6.2.5 of the Project Plan [17]. Furthermore, the underlying processes are described in the RAPL Implementation Process [9] and RAPL Design Process [10], respectively.
The development tools are documented in the Tool Overview and Assessment [16].

Test Strategy

The test strategy is described in detail in a separate chapter *Test Strategy* on page 6.

User and Technical Documentation

For a list of user and technical guides, please refer to chapter *References* on page 17.

User and technical guides are also available as Web Help.
Most user guides provide a context-sensitive access from the PharmaSuite® application.
All reviews have been conducted by subject matter experts. Reviews are informal, whereas all approvals are documented via DMS [3].

Risk Management

Risks that have been identified for FactoryTalk PharmaSuite 11.01.00 are provided in section 9 of the Project Plan [17].

Configuration Management

Configuration management followed the RAPL Configuration Management Process [8]. FactoryTalk PharmaSuite 11.01.00-specific information is provided in section 10 of the Project Plan [17].

Traceability

Traceability is described in detail in a separate chapter *Traceability* on page 9.

Quality Management

Quality Management is described in detail in a separate chapter *Quality Management* on page 10.

Project Monitoring and Control

More details on Project Monitoring and Control, based upon the approach described in chapter *Life-Cycle Methodology*, is provided in section 9 of the Project Plan [17].

Project Closure

The formal approval of the Project Closure Report [23] officially closed the project.

Further Development of the System

The remaining anomalies will be evaluated for resolution in future versions of the product.

Quality Risks

Known issues relevant for end users have been documented in the project's Release Notes [22].

Note: The qualification of FactoryTalk PharmaSuite 11.01.00 has been completed following a risk-based test approach focusing on all changes made to the product since the previous release. All changes have been analyzed and tested with regard to their risk and impact on the system.

Specification Artifacts

The focus of the requirements engineering process for FactoryTalk PharmaSuite 11.01.00 is to elicit, develop, manage, review, and approve requirements. These activities are performed to ensure that the team develops a product that addresses customer needs and market opportunities while aligning with business goals and objectives.

As a result of requirements elicitation practice, a set of requirements is established, documented, and maintained in the product backlog in the requirements management system Jama.
The product backlog is continuously maintained by adding, adjusting, grooming, and prioritizing the Product Backlog items to make sure the most valuable product is shipped to customers.
The refinement is a regular ongoing process in which the Product Manager, the Product Owner, and the Development Team collaborated on the details of the Product Backlog items. Thus, it is ensured that the Product Backlog reflects what the Development Team is working on and that the team understood the items in the Product Backlog to the level needed so that the value of the work the team performs is maximized.
During the sprint planning event(s) the teams determined the Product Backlog items they will work on during a sprint.

Finally, all of the relevant specification details, including use cases and requirements, have been compiled within the Supported Platforms Guide [24] and the Functional Requirement Specification (FRS) documents ([25] - [40]).

Requirements are subject to version control and base-lined per approved document. Baseline requirements are modified using change control per relevant QMS procedures. Changes have been tracked through the change control mechanism of the respective documents.

As a result, the Supported Platforms Guide and all FRS documents of FactoryTalk PharmaSuite 11.01.00 include all requirements and list all changes that apply to this release (compared to previous releases).

All specification documents have been posted on the Document Management System [3] for formal approval.

Test Strategy

The software test process is generally described in the RAPL Verification and Validation Process [6]. The document outlines the testing process as well as the entry and exit criteria of the different test types.

This chapter describes the framework requirements and methods of test planning. The detailed planning of test activities and their execution have been described in a Risk-Based Testing Guideline [15], with project-specific deviations defined in the Test Plan [18].

Principles of Test Execution

The objective of testing is the verification of the correspondence between the system and its specification. In order to achieve this objective, testing tried to reveal any deviation in the implemented functionality against requirements, use cases, and other specification artifacts. Anomalies found in the scope of testing have been recorded and analyzed. The majority has been resolved and verified according to the change control procedures and guidelines ([14], [11], [13]) until a high level of confidence had been assured that the system meets the specified requirements.

Structure of Test Documentation

The highest-level document is the Project Plan [17]. It lays out the general framework of requirements for test execution and for the structure of test plans and individual testing phases as well as the general test scope.

The Risk-based Testing Guideline [15] in combination with the project-specific Test Plan [18] constitutes the second level. It describes all activities of the testing phase. The testing phase reflects important milestones in the product development. A Test Summary Report was generated at the end of the testing phase [19]. The Test Summary Report corresponds to the Test Plan and gives a summary of all test activities and their results for that test phase.

Third level items are the System Impact Analyses, Risk Assessments, as well as Test Cases. The System Impact Analysis along with the Risk Assessment identifies and assesses the risk of changes related to the system. Based on the results, the required test scope has been derived. Details are defined in the Risk-Based Testing Guideline [15].

Prior to test execution, all test documents were reviewed and approved.

Document Management System

All quality-relevant documents and project documentation are subject to the organization's Document Management System [3]. Each document is numbered and version-controlled.

All documentation of FactoryTalk PharmaSuite 11.01.00 is generally stored following Rockwell Automation's Record Retention Procedure [5].

Evaluation of Test Results

Any defects found during test execution are documented in the defect management system as an anomaly.

The triage team is responsible for conducting an initial analysis on the anomaly submitted to determine the appropriate FMEA value following the FMEA guidelines as described in the Anomaly Management Process [11].

Repetition of Tests

The repetition of a test after a correction cycle followed the principle of regression testing (for details see RAPL Verification and Validation Process [6]). The tests to be executed during the repeated execution usually represent a subset of the original test cases. The selection process was geared by the System Impact Analysis and Risk Assessment, as described in detail in the Risk-Based Testing Guideline [15].

Implementation of corrective actions and regression testing was repeated until all anomalies violating the acceptance criteria (see [11] for details) were corrected and verified.

Testing Phases

The testing of FactoryTalk PharmaSuite 11.01.00 was conducted in phases. The typical course of testing was as follows:

- Creation of the Test Plan [18] (incl. review and approval)
- Creation or update of Test Cases [4] (incl. review and approval)
- Test execution and recording of results
- Classification of detected anomalies and definition of corrective actions
- Creation of a report summarizing the test results of the testing phase
- Review and approval of the Test Summary Report [19]

Prior to testing, an installation qualification for the software has been carried out with the objective to document the proper installation of software for all equipment used for the tests. This was executed based on the guidelines defined in the Risk-Based Testing Guideline [15].

Release Criteria

The test phase was accepted when all defined test cases had been completed (incl. review and approval) and the results of the execution of all tests were accepted and thereby no CRs violating the project's release criteria (as defined per [11]) were left.

Note: FactoryTalk PharmaSuite 11.01.00 provides add-on functionality to ProductionCentre and thus uses existing functionality of ProductionCentre.

During verification and qualification of FactoryTalk PharmaSuite 11.01.00, testing has been focused on FactoryTalk PharmaSuite 11.01.00 requirements. ProductionCentre was considered to be a qualified baseline for FactoryTalk PharmaSuite 11.01.00.

Test Environment and Tools

The list of hardware and software used for testing is captured in the Test Summary Report [19] and included in this document in *Appendix B: Test Equipment*.

Test Plan

A project-specific Test Plan [18] has been created, reviewed, and approved before start of test. See chapter *Test Planning* for more details.

Test Reports

After finalization of the system test, a report summarizing the test results of the testing phase has been created, reviewed, and approved [19].

In addition, all test cases have been listed in the Final Test Status Report [20].

Traceability

Traceability is maintained partially within a traceability matrix document, and partially within the different types of documents:

- Software requirements reference to market requirements.[1]
- Change requests in Jira reference to related requirements (in Jama) implemented and fixed.
- Code and design review protocols are documented at change requests in the change management tool.
- Each change request references in which build it was integrated.[2]
- Change requests list the changes to the system.
- Test cases (in qTest) reference to the requirements (in Jama) they are going to verify.

The traceability between test case and requirement is maintained per iteration as part of the "Done" state, the traceability matrix document [21] is finally uploaded to the Document Management System [3] for approval (prior to project completion). This document shows the mapping of requirements to test cases, thereby helping to ensure that all requirements have been verified.

[1] For releases 1.0 and 1.1 only, i.e. no new market requirements have been developed for FactoryTalk PharmaSuite 11.01.00 and traceability from software requirements to market requirements has not been maintained anymore for FactoryTalk PharmaSuite 11.01.00. Rationale: By using the iterative life-cycle methodology and the product backlog, a different method is applied to gear the prioritization of feature implementation. Furthermore, market requirements have not been used for formal tracking and have not been part of the formal testing approach, but were used for documentation and project control purposes only.

[2] Build numbers are increasing over time. Beware: Change requests may reference to a build that did not match acceptance criteria. However, the next number of a build meeting acceptance criteria also contains that change request.

Quality Management

Product and Process Quality

Product and process quality is assured through regular assessments.

Anomaly Management

Anomaly tracking has been done within Jira per the Anomaly Management Process [11]. The triage team reviewed and evaluated anomalies in regular meetings (frequency as needed) according to the Anomaly Management Process [11]. The triage team was led by the Product Owner. In this role, the Product Owner had the final decision in case of disagreement of the triage team. Further members of the triage team can be found in section 5.1 of the Project Plan [17].

Test Planning

This chapter discloses important information from the Risk-based Testing Guideline [15]. Parts that have not been transferred to this document may be reviewed during audits, as needed.

Test Approach

Testing was conducted to verify the stability of the product and the functionality based on the specification artifacts (e.g. requirements, use cases, etc.). The following sub-sections describe the types of testing that have been conducted on FactoryTalk PharmaSuite 11.01.00. The definitions for each testing type are defined in the RAPL Verification and Validation Process [6].

For the verification of FactoryTalk PharmaSuite 11.01.00, a risk-based testing approach has been applied (see [15]). In general the approach is defined as follows:

- Each new feature and functionality had to be analyzed through a risk assessment to determine the risk priority.
- All system changes (i.e. the corresponding Change Requests) needed to be analyzed within a System Impact Analysis (SIA) and a risk assessment had to be conducted to determine the necessity and rigor of testing.
- The risk-based approach was not applied to installation tests, installation qualification, unit tests, performance tests, and the final acceptance tests, as a variation of the test depth (level of detail) was not foreseen for these types of test cases.

Based on the various risk assessments, test cases have been created or revised to define the individual test scope. Sometimes, several features or functionalities have been combined into one test scenario.

Risk Evaluation

The risk-based approach is considered to establish a scalable science-based verification process and to ensure that the work and testing effort spent focuses on risky areas. Therefore, the risk evaluation was divided in two interrelated processes:

1. The first step of the risk evaluation is to identify all system areas affected with potential risk within the System Impact Analysis (SIA).
2. The second step is to rate the potential risk to get the risk priority as an indicator for the resulting testing or mitigation strategy.

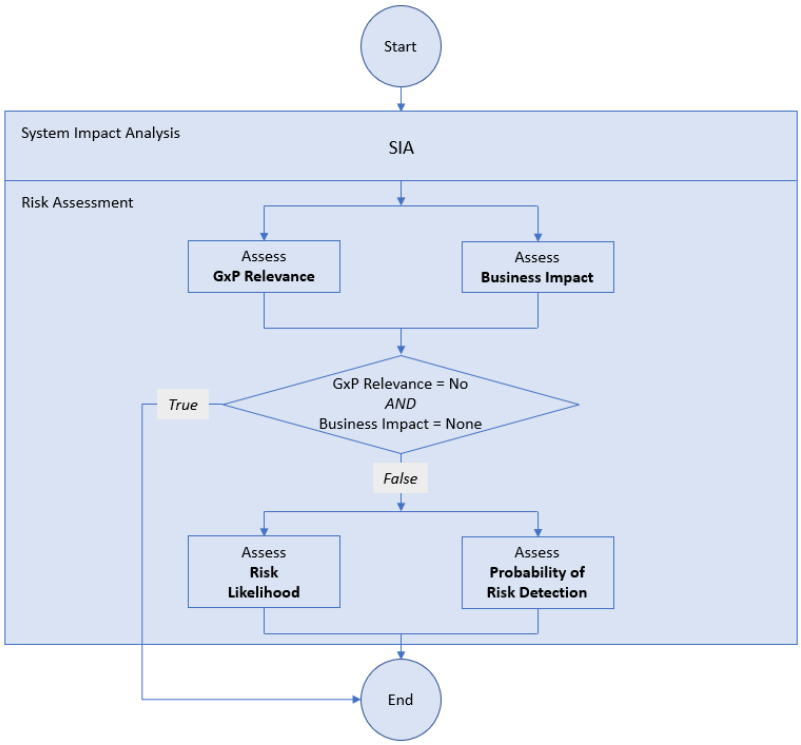

Figure 2: Risk Evaluation Process

System Impact Analysis (SIA)

All changes made to the system have to be listed and analyzed within the System Impact Analysis. This means every change (e.g. bug fixes, new functionalities) needs to be analyzed to identify all system areas with potential risk (e.g. by side effects) caused by the changes. The System Impact Analysis identifies affected system areas as a first indication of the appropriate scope of testing.

Risk Assessment (RA) Process

The risk assessment aims to classify the risk to the different functionalities of FactoryTalk PharmaSuite 11.01.00 using pre-defined assessment criteria.

Adapted from this, a Subject Matter Expert derived the appropriate risk priority for each function. The risk assessment was performed based on specification artifacts identified during the System Impact Analysis process.

The assessment of the GxP Relevance and Business Impact are artifact-specific attributes and therefore independent of the change. These classifications have been documented per specification artifact in the System Impact Analysis (SIA) & Risk Assessment (RA).

Guidelines for risk assessment are described in detail in the Testing Guideline [15].

Testing Scope

Unit Tests

JUnit has been used for unit testing where applicable (up to and including the service layer). Therefore, the public interfaces of MES components have been tested. Unit testing followed the RAPL Unit Testing Guideline [7]. The tests were managed within the source code repository like ordinary source code.

More details regarding Unit Tests can be found in the Risk-based Testing Guideline [15].

Installation Test

The installation test was aimed to check the correct implementation and description of the FactoryTalk PharmaSuite 11.01.00 installation process including the configuration for all components.

The installation process was based on the description of FactoryTalk PharmaSuite 11.01.00's Installation Guide [44].

Feature Tests

All feature tests were based on the specification artifacts, refer to chapter *Specification Artifacts*, page 5.

Note: Parts of the feature tests have been realized as automated tests. However, independent of the used technique, there is no difference to the claim of the tests. Both, automated as well as manual tests have been treated as equally qualified test methods.

Performance Tests

Performance tests (as well as stress tests, boundary tests, limit tests, and response tests) are implicitly covered within the feature tests. The performance test scope was covered within the System Impact Analysis [41] and [42].

Reliability Tests

The objective of reliability testing was to show the system running 12+ hours, performing operations like insertions and deletions of master data. Therefore, special scripts have been run to verify the reliability as described. Reliability tests have been performed in the qualified test environment.

Integration Tests

Integration tests for new features or functionalities as well as CRs have been covered within the feature or regression tests. The integration test scope was covered within the System Impact Analysis [41] and [42].

System Tests

System tests as described in the RAPL Verification and Validation Process [6] have been covered within the corresponding risk evaluation and the resulting regression tests. Therefore, no additional system tests were required.

Customer Acceptance Testing

Customer acceptance tests were not planned for FactoryTalk PharmaSuite 11.01.00.

Regression Tests

Regression testing of FactoryTalk PharmaSuite 11.01.00 was based on a risk assessment, which results in the potential risks and impact of any code change (defect resolution or feature). The impact is evaluated with regard to existing functions.

Regression testing was executed by re-running feature tests that had been executed in previous releases against the current system. The objective was to ensure that the functionality of the system continues to work as expected after all features have been implemented and defects have been resolved. The scope has been derived by and described in the respective risk evaluation of the System Impact Analysis ([41] and [42]).

Note: Parts of the regression tests have been realized as automated tests. However, independent of the used technique, there is no difference to the claim of the tests. Both, automated as well as manual tests have been treated as equally qualified test methods.

CR verification

Change requests (CRs) integrated in the system were objects of this test, as long as they were not covered by other tests. The verification of CRs ensures that anomalies have been resolved satisfactorily.

Final Acceptance Tests (FAT)

The final acceptance test represented a high-level, overarching test scenario in the course of FactoryTalk PharmaSuite 11.01.00 qualification. It examined the functional capability of the system installed based on the final build[3]. The objective of the final acceptance test was to examine the system applicability in the operational area and to confirm the product satisfies the criteria for the customer.

Integrated Solutions Testing

Within this project, no integrated solution tests were planned.

Requirements Traceability

A traceability matrix [21] has been generated to trace the test cases to the appropriate requirement(s) and other specification artifacts. The matrix has been developed throughout the testing activities as new test cases were created and executed or as specifications changed.

Test Team and Responsibilities

The test team members and responsibilities are called out in the Project Plan [17].

[3] "Final" in the sense that this is the final build of the current release, the build that is going to be shipped.

Test Environment

For the execution of tests, dedicated virtual machines available in the Enterprise Development as a Service (EDaaS) CI/CD environment of Rockwell Automation have been used. Thus, all testing has been performed with clients and servers running in the Azure cloud (hosted by Microsoft).

All test equipment used for official tests has been installed according to the specifications.

For more details, refer to *Appendix B: Test Equipment*.

Installation Qualification

The objective of the installation qualification was to check the suitability of the virtual machines as far as dedicated to FactoryTalk PharmaSuite 11.01.00, as well as software components related to FactoryTalk PharmaSuite 11.01.00 installation. The installation qualification was performed on the test environment before start of formal testing.

For this specific test, no acceptance criteria were defined. The software installed on the clients and servers must correspond to the definitions in the Supported Platforms Guide [24]. Otherwise, the client or server must not be used within the official test. The software installation qualification refers to all clients and servers mentioned in the Supported Platforms Guide [24].

Glossary & Abbreviations

Term	Definition
CR	Change Request A record that describes a request to change the system and may be a story, an anomaly, etc.
Done state	Final state of a product backlog item indicating that all related tasks (e.g. specification, implementation, test, documentation) have been completed.
FRS	Functional Requirements Specification Includes detailed software requirements (FTPS-FR-<unique identifier>)
IDS, IDSs	Integrated Design Specification(s)
Jama	Requirements management system used by Rockwell Automation
Jira	Change management system used by Rockwell Automation
MES	Manufacturing Execution System
PBL	Product Backlog Prioritized list of items to be realized in PharmaSuite
qTest	Test management system used by Rockwell Automation
Triage	Process of deciding upon further processing of CRs (resolving, deferring, etc.).
Triage team	Team of subject matter experts, led by the Product Owner, performing the triage process.

References

[1] ICH Q9 Quality Risk Management; International Conference On Harmonisation Of Technical Requirements For Registration Of Pharmaceuticals For Human Use; Step 4, version 09-Nov-2005

[2] GAMP® 5: A Risk-Based Approach to Compliant GxP Computerized Systems; (Second Edition); ISPE; 2022

[3] Rockwell Automation Document Management System (DMS), basic functionality included in central SAP

[4] Rockwell Automation Testing Environment, https://ra.qtestnet.com/

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[5] Record Retention Procedure (900-20-33)

[6] RAPL Verification and Validation Process (BSRC-4837)

[7] RAPL Unit Test Guideline (part of Implementation Process) (BSRC-4883)

[8] RAPL Configuration Management Process (BSRC-4740)

[9] RAPL Implementation Process (BSRC-4737)

[10] RAPL Design Process (BSRC-4733)

[11] Anomaly Management Process (BSRC-5515)

[12] MES Binding Work Instructions (100-01)

[13] Processing of Anomalies (107-07)

[14] Processing of Stories (108-01)

[15] Risk-Based Testing Guideline (105-07)

[16] FTPS 11.01.00 – Tool Overview and Assessment

[17] FTPS 11.01.00 – Project Plan

[18] FTPS 11.01.00 – Test Plan

[19] FTPS 11.01.00 – Test Summary Report

[20] FTPS 11.01.00 – Final Test Status Report

[21] FTPS 11.01.00 – Traceability Matrix

[22] FTPS 11.01.00 – Release Notes

[23] FTPS 11.01.00 – Project Closure Report

[24] FTPS 11.01.00 – Supported Platforms Guide

[25] FTPS 11.01.00 - FRS Data Management

[26] FTPS 11.01.00 - FRS Recipe and Workflow Management

[27] FTPS 11.01.00 - FRS Execution Framework
[28] FTPS 11.01.00 - FRS Execution Viewer
[29] FTPS 11.01.00 - FRS Review and Approval
[30] FTPS 11.01.00 - FRS Runtime Data Management
[31] FTPS 11.01.00 - FRS Non-functional Requirements
[32] FTPS 11.01.00 - FRS DCS Phases
[33] FTPS 11.01.00 - FRS Dispense and Inline Weighing
[34] FTPS 11.01.00 - FRS EBR Phases
[35] FTPS 11.01.00 - FRS Equipment Automation Phases
[36] FTPS 11.01.00 - FRS Equipment Tracking Phases
[37] FTPS 11.01.00 - FRS IPC Phases
[38] FTPS 11.01.00 - FRS Material Tracking Phases
[39] FTPS 11.01.00 - FRS Output Weighing
[40] FTPS 11.01.00 - FRS Warehouse Management
[41] FTPS 11.01.00 – Artifact Specific Risk Assessment
[42] FTPS 11.01.00 – System Impact Analysis (SIA) & Risk Assessment (RA)
[43] Implementation of 21 CFR Part 11 – FactoryTalk PharmaSuite 11.01.00
[44] FTPS 11.01.00 - TG Installation
[45] FTPS 11.01.00 - TG Installation – Upgrade
[46] FTPS 11.01.00 - TG Installation - Building Blocks
[47] FTPS 11.01.00 - TG Administration
[48] FTPS 11.01.00 - TG Configuration and Extension
[49] FTPS 11.01.00 - TG Developing System Building Blocks
[50] FTPS 11.01.00 - TG Phases of the DCS Package
[51] FTPS 11.01.00 - TG Warehouse Management
[52] FTPS 11.01.00 - UG Production Management
[53] FTPS 11.01.00 - UG Recipe and Workflow Designer
[54] FTPS 11.01.00 - UG Data Manager
[55] FTPS 11.01.00 - UG Production Execution
[56] FTPS 11.00.00 - UG Production Inventory
[57] FTPS 11.01.00 - UG Production Execution Viewer
[58] FTPS 11.01.00 - UG Production Responses
[59] FTPS 11.01.00 - UG Dispense and Weighing Phases
[60] FTPS 11.01.00 - UG EBR Phases

[61] FTPS 11.01.00 - UG Material Tracking Phases

[62] FTPS 11.01.00 - UG Equipment Phases

[63] FTPS 11.01.00 - UG IPC Phases

[64] FTPS 11.01.00 - UG DCS Phases

[65] FTPS 11.01.00 - UG Warehouse Management

Note: For DIR numbers and latest revisions of the FTPS 11.01.00-specific documents, refer to “FTPS 11.01.00 - Documents and Approvals”, DIR 10007172713 /REV.

Approvals

Approvals are captured electronically on the organization's Document Management System [3]. The required approvers of this document include the following:

Role	Name
Product Manager	Andreas Grossmann
Engineering Manager	Steffen Landes
Quality Manager	Eva Mueller

Revision History

The following table describes the history of this document. Each version has been approved per Document Management System [3].

Version	Author	Description
1.0	Gaurav Bindal	Initial version created.
1.0	Eva Mueller	Final update.

Appendix A: System Boundary Definition

Current Situation

PharmaSuite provides audit trail as required by regulations in different ways, see "Implementation of 21 CFR Part 11 – FactoryTalk PharmaSuite 11.01.00" [43].

In addition, raw data is recorded for creation, modification, and deletion of objects in *Process Designer*. However, this data is neither exposed nor usable as is for audit trail review, reporting etc., but requires additional steps to become meaningful (*not subject to standard PharmaSuite product offering*).

Audit trail data for objects in *Process Designer* are not required by any regulation. The rationale is explained in further detail in subsequent sections.

Process Designer allows to implement a fine-granular authorization scheme on two levels: Access can be granted or denied on *object type* (e.g. "Lists") or *individual object* (e.g. list "CostCenters") level. Furthermore, different privileges can be assigned for different actions like creation, modification, and deletion.

Controls for GMP Data

The basic question is: "Do all changes to data and records that (may) have an impact on data integrity or product quality need to be subject to a computer-generated audit trail or not?" From a compliance perspective, the answer is clearly "No".

Instead, a risk assessment should be applied. The result of this risk assessment identifies the critical data and records, describes the criticality and risk of uncontrolled changes and deletion, and defines risk management measures to eliminate, mitigate, or accept an identified risk.

Implementing (or activating) an audit trail is one amongst several possible measures, but clearly not the only one. Alternative measures must provide adequate controls and include, but are not limited to

1. the application of rigorous, documented change or version control (in combination with access control) or
2. security measures to prevent or avoid accidental and unauthorized changes (e.g. storage on read-only media).

PharmaSuite's Boundary

Drawing the Line

As any other system, PharmaSuite has a boundary. Within this boundary, PharmaSuite fully complies with GMP aspects, specifically the tracking of changes to GMP data that may have an impact on data integrity or product quality.

Some data that is managed in PharmaSuite – it should be distinguished from other data managed in other applications (e.g. *Process Designer*), thereby defining the boundary. This chapter should help with the disambiguation.

Inside

All master and runtime data that can be created, altered, or deleted *by means of the PharmaSuite UI* is considered *inside*. "Implementation of 21 CFR Part 11 – FactoryTalk PharmaSuite 11.01.00" [43] describes the various manifestations of audit trail for this data – the 'classical' audit trail for material, the transaction history for inventory objects, the change history and logbook for equipment, the batch record for produced batches, etc. All this data resides *inside* the boundary of PharmaSuite.

Outside

All configuration and build-time data that *cannot* be created, altered, or deleted by means of the PharmaSuite UI (this data is typically setup once during system deployment) is considered *outside*. This data is subject to system validation and installation qualification processes. Changes in the operational phase may be recorded and made available via 'audit trail', but this is not a regulatory requirement. However, changes need to be controlled by means of good engineering practices.

This applies to many objects managed in *Process Designer* – incl. forms, reports, flexible state models etc. As changes to these objects can have a severe impact on the PharmaSuite application itself, access to this data needs to be strictly limited to dedicated persons. This is no different than access control to other deployment-relevant components like database or application server.

Example

As an example and to highlight the different dimension and scope of a change, alterations to a master recipe can be made visible by the comparison capabilities in PharmaSuite and will be reviewed and approved before going into production. While an error (that would affect all future orders based on this master recipe) would already be serious, all other master recipes are not affected at all when changing a master recipe. In contrast to this, changes to the *MESMasterRecipeVersionGraph* flexible state model (FSM; the default version graph for master recipes) have a global impact on the review and approval workflow of all master recipes. This kind of change clearly requires different handling.

Recommendation

When combining the previous sections, it becomes obvious that (changes to) GMP data *inside* PharmaSuite is handled differently compared to (changes to) GMP data *outside* this boundary: Whereas a comprehensive audit trail is available for the first, data outside of PharmaSuite requires rigorous, documented controls.

The basic assumption is that changes to configuration and build-time data are not daily business, but rather exceptions, justifying a more rigorous and securer process.

Implementation of Controls

The various options to set up, administer, and configure PharmaSuite are described in several *Technical Guides*. After the initial system setup (and validation), any changes to configuration and build-time data made outside of PharmaSuite require a defined change control process.

Separation of Duties

The change control process applied to data in *Process Designer* should be reinforced by making adequate use of *Process Designer's* access privileges, thereby implementing a scheme to support clear *separation of duties*.

Appendix B: Test Equipment

The following sections describe the hardware and software components used for testing of FactoryTalk PharmaSuite 11.01.00. This does not mean that other hardware or software is unsuitable to run FactoryTalk PharmaSuite 11.01.00.

In general, FactoryTalk PharmaSuite 11.01.00 can run on any standard hardware that is sufficiently equipped regarding CPU, RAM, etc., so the listed servers and clients should be taken as examples only.

For suitable software components, please refer to the Supported Platforms Guide [24].

If different hardware or software components are used, the impact and risk of the different components should be evaluated and testing conducted, as appropriate.

Server Hardware Components

All testing has been performed with logical servers running on Virtual Machines (VMs) in the Azure cloud (hosted by Microsoft) and were created on demand. These are configured with an Intel(R) Xeon(R) Platinum 8370C CPU @ 2.80GHz, disk space (HDD) of 100GB and memory (RAM) of 33GB.

Additionally, VMWare ESXi for 1 logical server VM for application (JBoss) and database (Oracle) server for migration was used.

Server Name	CPU[4]	HDD	RAM
EUDEKARQAESXI4	2x Intel XEON E5-2620 / 2.4 GHz (24 cores)	2x 5.46 TB	196 GB

The virtual machines for the logical migration servers running on the above-mentioned HW servers have been configured as follows:

VM Name	Server Name	Purpose	HDD	RAM
QAS010	EUDEKARQAESXI4	JBoss + Oracle	40 GB	12 GB

Client Hardware Components

Client virtual machines in the Azure cloud (hosted by Microsoft) were created and used on demand. These are configured with an Intel(R) Xeon(R) Platinum 8370C CPU @ 2.80GHz, disk space (HDD) of 64 GB, and memory (RAM) of 16 GB

[4] The number of cores is based on hyper-threading, i.e. the physical number of cores is half of it.

Server Software Components

Please note that the language configuration of the operating system for the test system must be English[5].

Category	Type of Software	Software and Version
Application / Database Server	Operating System	Microsoft Windows Server 2019
	DBMS	Oracle 19c Enterprise Edition, 19.0.0.0.0
	Application Server	JBoss EAP 7.4.9.GA
Client Software Components	Operating System	Microsoft Windows 10 Enterprise LTSC
	Browser	Google Chrome, 100.0.4896.88

[5] Locale = English (U.S.)